REMARKS

The allowance of claim 14 is acknowledged. The indication that the subject matter of claim 4 would be allowable is likewise acknowledged, and claim 4 has now been canceled and incorporated into claim 1. The indication that claim 13 would be allowable is further acknowledged, and the subject matter of claim 13 has now been incorporated into claim 22. Accordingly, it is believed that independent claims 1, 14 and 22, and the claims dependent thereupon, should now be allowed.

The rejection of claims 15 and 25 under 35 U.S.C. § 103(a) based upon the Korean IPO Publication No. 10-2000-0072201 (hereinafter "Kim") in view of the disclosure of U.S. Patent No. 6,268,147 to Beattie et al. (hereinafter "Beattie et al.") is respectfully traversed. The subject matter of claim 15, as amended, and the subject matter of claim 25 would not be obvious from the disclosure of Kim, as potentially modified by the disclosure of Beattie et al.

Kim proposes a method for diagnosing fragile X syndrome using DNA probes. So far as Applicant has been able to determine, this Korean publication has not issued as a Korean patent, and it has not been filed in any other country in the world. Kim proposes to cut DNA with restriction enzymes designed to free the environs of the FMR1 gene from the remainder of the chromosome. Kim then adds (1) labeled probes which have multiple triplets of CGG, (2) labeled probes that have multiple triplets of GCC, (3) sense and antisense DNA probes having different labeling material that will bind with some internal sequence within the FMR1 gene, and (4) two different biotinylated sense and antisense DNA probes that bind with some other internal sequence of the FMR1

gene. The mixture is then treated at high temperature to denature the double-stranded DNA and then allow hybridization reactions to occur where probes will affix themselves to the denatured, single-strand DNA being analyzed. Thereafter, the hybridized mixture is applied to a microwell plate having streptavidin coated within the microwells to sequester the last-added biotinylated probes and washed to remove everything that has not hybridized to FMR1 gene DNA to which a biotinylated probe has hybridized. Thereafter, reading of the signals of the two different fluorescent labels, e.g. CY5 and CY3, is carried out, and diagnosis is made based upon the relative strength of these two signals.

Comparison of the Kim protocol with Applicant's claims 15 and 25 shows that Kim does not use pairs of forward and reverse primers in combination with PCR amplification wherein the forward primers carry an anchoring moiety, that Kim does not obtain single-stranded product from the amplified DNA by digesting the antisense strand with an exonuclease, and that Kim does not then hybridize labeled target oligonucleotides with the single-stranded product, which targets may all contain the same fluorescent dye. After separating the hybridized product from the remainder of the mixture through the use of the anchoring moieties already in place, the target oligonucleotides that had hybridized are separately recovered apart from the remainder of the amplified DNA, and then this recovered labeled target is caused to hybridize to a microarray from which the relative signals are read where the signals from same fluorescent material may be read at different locations, assuming accurate comparisons. In addition to all of these differences, it is submitted that Kim's proposed use of two sets

of triplet probes, one with CGG triplets and the other with GCC triplets, would pose substantial potential difficulties from the standpoint that these probes would seem to have a very high tendency to hybridize with each other, as well as with the repeats in the FMR1 gene, and such could well affect the accuracy of the Kim diagnosis which has only a finite amount of patient DNA for analysis.

While it is true that Kim does mention both a Southern blotting technique and a PCR amplification technique as being examples of prior art techniques, Kim alleges that his invention, in not employing either Southern blotting or PCR amplification, is an improvement over these prior art techniques; thus, in this respect Kim is teaching away from Applicant's claimed invention.

The citation of Beattie et al. is stated to be merely for its teaching of the use of microarray technology to capture single-strand nucleic acid, which is admittedly well known. However, a microarray would not be useful with the Kim technique, as the same strands of the single-strand FMR1 gene being analyzed will likely have both of Kim's labeled probes hybridizing thereto. Thus, such a substitution of a microarray for a simple streptavidin coated microwell device would serve no useful purpose. The difference, of course, lies in the fact that Kim does not practice Applicant's procedure of first capturing all of the amplified strands of interest to which labeled target material has hybridized, washing to remove all non-captured target material, and then releasing the captured target material and separately analyzing such. In view of the foregoing, it is requested that the rejection of independent claims 15 and 25 based upon the combination of the disclosures of Kim and Beattie et al. be reconsidered and withdrawn.

In summary, it is believed that all five independent claims No. 1, 14, 15, 22 and 25 are in allowable condition and, in the absence of more pertinent prior art, that these claims, along with dependent claims 2, 3, 5-13, 16, 23, 24, should be allowed. Favorable action at an early date is courteously solicited.

Respectfully submitted,

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